



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

March 8, 2013

The Honorable Thomas McLain Middleton
Chairman
Senate Finance Committee
11 Bladen Street, 3 East
Annapolis, MD 21401

The Honorable Peter A. Hammen
Chairman
House Health and Government Operations
Committee
6 Bladen Street, Room 241
Annapolis, MD 21401

Dear Chairmen Middleton and Hammen,

I am writing to provide you with an update on regulation of surgical abortion facilities in Maryland. In this letter, I will provide background on the regulations and provide an interim report on the initial round of surveys.

Background

In July 2011, the Department began a stakeholder process to develop regulations for surgical abortion providers under Health General Article 20-209, which states:

The Department may adopt regulations that: (1) Are both necessary and the least intrusive method to protect the life or health of the woman; and (2) Are not inconsistent with established medical practice.

Stakeholders involved in the process included the Maryland Catholic Conference, Planned Parenthood of Maryland, and others. Over the course of the next several months, the Department shared draft regulations with stakeholders, reviewed nearly 1200 comments from the public, and made changes based on the constructive feedback received.

In July 2012, the Department published rules that for the first time made Maryland surgical abortion facilities subject to licensure.¹ The regulations cover the administrator's responsibilities; qualifications of physicians and other staff; surgical abortion procedures; anesthesia services; emergency services, including transfer of patients to a hospital; pharmaceutical services; laboratory and radiologic services; medical records; patients' right and responsibilities; physical environment; and the quality assurance program.

¹ Like other medical procedures, a licensed physician must perform surgical abortions. The new regulations supplement state oversight of licensed physicians and other health care professionals.

Since that time, the Department's Office of Health Care Quality (OHCQ) has made steady progress toward full implementation. These steps have included:

- Developing protocols and procedures for conducting surveys and addressing complaints.
- Developing and conducting internal training programs for surveyors, including a review of directly applicable and related regulations and professional standards of care.
- Developing a full-day training program for the staff of surgical abortion facilities and offering the program twice in October 2012.
- Establishing contact with, obtaining an application from, and approving initial licensure of surgical abortion facilities.
- Identifying other Maryland facilities potentially subject to the rules that have not applied for initial licensure and investigating to assure that there are no surgical abortion facilities operating outside of regulatory oversight.

Surveys of Surgical Abortion Facilities

Over the past several weeks, OHCQ has initiated surveys at the 16 surgical abortion facilities currently operating in the state. These have included both initial regulatory surveys and investigations in response to specific complaints. The survey process includes review of medical records, review of policies and procedures, interviews of patients and staff, observation, and other methods of gathering information as needed.

As planned and as noted in a February posting to the OHCQ website, this first round of surveys is expected to be complete by the middle of April.

So far, on initial survey, thirteen regulated facilities were found to be free of deficiencies that presented an immediate and serious threat to the health and safety of patients. However, earlier this week, the Department suspended licenses held by Associates in OB/GYN Care, LLC, to perform surgical abortions at three locations pending the correction of deficiencies.

The deficiencies at the OB/GYN Care sites related to preparedness for and response to emergencies. These included:

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- **Baltimore City location.** Surveyors identified a deficient response by facility staff to a cardiopulmonary arrest in a patient. The responding physician was not certified in CPR, and no attempt was made to use the Automated External Defibrillator (AED). In addition, during the survey, the AED was not operational.
- **Silver Spring Location.** Surveyors found deficient care of a patient, who, after undergoing an abortion, was left alone in the procedure room for approximately 3 minutes. When the patient began to awaken, she was at risk for falling and otherwise injuring herself.
- **Landover location.** Surveyors noted deficiencies in emergency readiness. The AED's pads had expired; the clinical nurse on site did not know how to use the AED or the suction machine; the nurses had not been trained on the use of the AED or the suction machine; and the suction machine did not work, because an adapter was missing.

To resume performing surgical abortion procedures at these facilities, Associates in OB/GYN Care will need to submit an appropriate plan of correction, implement the plan of correction, and have no other identified serious deficiencies. Associates in OB/GYN Care may provide other services at the three locations while its licenses for the performance of surgical abortion procedures at these facilities are suspended.

Conclusion

There has been significant progress implementing new regulations on surgical abortion facilities, which are important for access to care and patient safety. Under the regulations, surgical abortion facilities that either fail to seek licensure or fail to meet acceptable standards will not be permitted to operate in Maryland.

We will continue to provide updates to the legislative committees as this new regulatory program moves forward.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Joshua M. Sharfstein'.

Joshua M. Sharfstein, M.D.
Secretary